



<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/002,038	LEMUS ET AL.	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 12 October 2004.  
 2a) This action is **FINAL**.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 26 February 2002 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

This Office Action is in response to Applicant's amendments filed on October 12, 2004.

Claims 1-21 are pending.

### ***Drawings***

The formal drawings submitted on February 26, 2002 have been reviewed by the Examiner and are found to be acceptable. No new drawings are required.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7, 11-15, 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,830,683 to Hendricks et al.

Hendricks et al teach an indicator system for determination of sterilization. In one embodiment, the indicator system comprises a container (10) having an opening (11) at one end. A sterilization indicator agent is placed into the container. The sterilization indicator agent may be a chemical indicator (col. 10, lines 64-67) or a biological indicator (col. 8, lines 63-67), as recited in claims 2 and 3. Hendricks et al teaches that a compressible material is placed as a plug (foam insert) in the opening of the container. The plug serves as the only pathway for a sterilizing agent to enter the container. The foam insert regulates the amount of sterilizing agent reaching the test indicator (col. 7, lines 1-12). At col. 4, lines 44-52, the reference teaches

that precise positioning of the plug allows the diffusion to the indicator to be variable, thus providing variable diffusion restriction into the indicator. With respect to claim 4, the plug-filled opening constitutes the diffusion pathway into the container. With respect to claims 5, 11 and 18, Hendricks et al teach the length of the plug to be inserted into the container is adjustable (col. 7, lines 33-57). With respect to claim 7, Hendricks et al teach that the plug may be made of foam or sponge material have multiple pores or cells. With respect to claim 12, the reference teaches that a combination of materials (such as polyurethane, polyester, polyether, cellulose, etc) may be used. Further, the foam density, pore size, cell structure, size, shape and amount of foam may be adjusted according to the particular situation (col. 7, lines 13-24; col. 11, lines 19-30), as recited in claims 13, 15 and 19. With respect to the method of assessing sterilization efficacy, Hendricks et al teach determining an environmental parameter (feature), placing the sterility indicator into a sterilizer with other items to be sterilized, making adjustments to the compressible material (such as decreasing the density), conducting the sterilization cycle and determining the efficacy of the sterilization process by observing the chemical or biological indicator.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 6, 8-10, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hendricks et al in view of US Patent 5,801,010 to Falkowski et al.

The disclosure of Hendricks et al is described above. Hendricks et al disclose first and second members (50, 51) in a telescoping relationship and having openings. However, this embodiment of Hendricks et al differs from the instantly claimed invention in that there is no disclosure of one member serving as an adjustable cover for the openings.

Falkowski et al teach a sterilization indicator having a container similar to the embodiment of Figure 5 in Hendricks et al. The container of Falkowski et al comprises first and second members (12, 28) that are disposed in a telescoping relationship. Both the first and second member have openings/slots (16, 32) disposed thereon. The openings permit sterilant to penetrate the container and reach the indicator. Once in a closed position, member 28 covers the openings on member 12 and vice versa. Although the reference does not explicitly teach such, the mere operation of the device of Falkowski et al suggests that member 28 serves as an adjustable covering for the openings on member 12 since the openings provide the means by which sterilant reaches the indicator and because members 12 and 28 slide together to form a single unit. See col. 4, lines 34-43, col. 5, lines 23-26, 31-34.

It would have been obvious to one of ordinary skill in the art to allow the telescoping member to serve as an adjustable cover for the openings in the device of Falkowski et al to provide a means for restricting the flow of sterilants into the container.

***Response to Arguments***

6. Applicant's arguments filed on October 12, 2004 have been fully considered but they are not persuasive.

With respect to the anticipation rejection over Hendricks, Applicants argue that Hendricks teaches a fixed resistance and fails to teach a variable resistance as claimed. Applicants' argue that the goal of Hendricks is to have each sterility indicator to be manufactured in a consistent fashion.

In response, the Examiner would like to highlight col. 7, lines 5-13 and lines 45-57. Hendricks clearly teaches that the plug inserted into the sterilization container is the only pathway to allow sterilant to enter. The foam plug regulates the amount of sterilant that actually enters. The reference further teaches that the foam insert is adjustable and variable in its ability to change according to the different sterilization situations and protocols. Thus, the foam insert of Hendricks does not function to maintain a fixed resistance – in fact, its function is to adjust and vary according to different sterilization situations. The reference teaches that a mere change in the length of the plug is sufficient to effect a change in the sensitivity of the indicator to the sterilization process, just as Applicants have claimed.

With respect to the obviousness rejection over Hendricks in view of Falkowski, Applicants argue that Falkowski teaches either having all of the openings open or all of them closed. Applicants argue that the Examiner has used hindsight in concluded that some of the

openings in Falkowski may be opened/closed. In response, the closing member (28) of Falkowski is indeed adjustable and no hindsight is needed to support such a conclusion. Falkowski teaches, with respect to figure 1, that member (28) covers the openings on member (12) and vice versa. Since the openings are in vertical alignment with one another, the movement of members 28 and 12 could not possibly open and close each opening simultaneously, so as to make the openings either open or closed. For instance, where member 28 is moved downward, the first opening 16 will be covered first. Further downward movement would cause the second opening 16 to be covered, and so forth. Thus, the cover of Falkowski is adjustable in its ability to open and close the openings that allow sterilant into the container.

***Citation of Relevant Prior Art***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6,825,972 to Jacobs et al teaches a sterilizing device comprising a diffusion restriction. The diffusion restriction may be in the form of the clearance between cup 42 and housing 38 (shown in figure 6), a permeable membrane (shown in figure 7) or plurality of holes regulated by valve 84 (shown in figure 8). A biological indicator may also be included in the container (col. 8, lines 47-52).

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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